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In re application of: NICOLETTE
USSN: 09/870,216
Filed: May 30, 2001
For: Therapeutic Compounds for Ovarian Cancer

Transmitted herewith is a Communication In Response to Restriction Requirement (5 pgs).

Group Art Unit: 1642
Examiner: Misook Yu, Ph.D.

Patent
Our Docket: 5028

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Charles A. NICOLETTE

Serial No.: 09/870,216

Filed: May 30, 2001

For: THERAPEUTIC COMPOUNDS FOR OVARIAN CANCER

Art Unit: 1642

Examiner: Misook Yu

Commissioner for Patents
P.O. Box 1450
Alexandria, VA22313-1450

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING FACSIMILE TRANSMITTED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE FACSIMILE NUMBER (703) 872-9306 (Right Fax) ON JUNE 10, 2004.

June 10, 2004
Date

Deborah A. Dugan
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Response to Restriction Requirement

This Communication is being filed in response to a Restriction Requirement mailed May 11, 2004 in connection with the above-identified application. A response to this Restriction Requirement is due on June 11, 2004. Accordingly, this response is timely filed.

REMARKS

Claims 1-9 are pending in the subject application and are subject to a restriction requirement and species election.

Requirement for Restriction under 35 U.S.C. §121

In the May 11, 2004 Office Action, the Office requires restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

Group I	Claims 1-3, drawn to compositions comprising at least two immunogenic ligands, classified in class 530, subclass 300.
Group II	Claims 4-8, drawn to host cell, classified in class 424, subclass 93.1.
Group III	Claim 9, drawn to a method of inducing immune response using composition comprising at least two immunogenic ligands, classified in class 424, subclass 184.1.

Noting that Groups I-III contain claims generic to a plurality of patentably distinct species (listed in independent claims 1, 4 and 9) as SEQ ID NOs: 3, 5, 7, 9 and 11, the Office further requires an election of two SEQ ID NOs as a species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Request for Reconsideration under 37 C.F.R. §1.143

Applicant respectfully requests reconsideration and modification of this restriction and species election requirement. The presently claimed inventions are drawn to compositions comprising *at least two* of 5 specifically defined peptide sequences, host cells comprising *at least two* of 5 specifically defined peptide sequences, and methods utilizing compositions comprising *at least two* of 5 specifically defined peptide sequences.

The Office has recently instituted a policy directed to improving restriction practice within TC 1600 as stated by the recent publication of the TC1600 Restriction Practice Action Plan (press release on October 6, 2003). This policy emphasizes the importance of the quality and consistency of restriction practice and recognizes the need for improvements in this complex technology unit.

As stated by the Office, there are two criteria for a proper requirement for restriction between patentably distinct inventions, MPEP 803. First, the inventions must be independent or distinct. Second, there must be a serious burden on the Examiner if restriction is required. The Examiner must examine the subject application on the merits even if it includes claims to distinct inventions if such an examination can be made without serious burden. Applicant asserts that the search of claims 1-9 does not comprise a serious burden.

Independent claims 1, 4, and 9 each contain a Markush grouping comprising 5 specifically defined peptide sequences. According to MPEP § 803.02. the Examiner must examine all members of the Markush group in the claims on the merits even if they are directed to independent and distinct inventions, if the examination can be made without serious burden.

> "If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions." MPEP § 803.02.

Applicant submits that these independent claims 1, 4, and 9 can be searched without serious burden.

First, the Office is capable of readily performing sequence searches of peptide sequences. The peptide sequences present in the instant claims are relatively uncomplicated. They uniformly consist of only 9 amino acids. Many sequences have similar characteristics such as shared anchor residues. Additionally, Applicant has provided a sequence listing for the instant sequences. These factors indicate that an examination of the peptide sequences contained in the Markush group of the instant claims can be reasonably performed.

Second, Applicant notes that chemical cases with Markush groups, which often contain complicated chemical R group structures, are routinely searched without restriction. The instant claims do not contain complicated R groups. Rather, a search of the instant peptide sequences constitutes straight sequence searching. The different

standard that the Office appears to be applying for Markush groups containing peptide structures is unsupported.

Third, the Office operates under a policy wherein 10 nucleotide sequences constitute a reasonable number for examination purposes, MPEP § 803.04. This allows for the examination of up to ten independent and distinct sequences in a single application without restriction. There are no distinct limitations on nucleotide sequence length and complexity in this policy, suggesting that potentially long or complicated sequences (likely longer and more complex than the 9-mer instant peptides) are considered reasonable to search. The Office also provides guidelines for the search of combinations of 10 or more individual sequences where they are claimed.

As stated in MPEP § 803.04:

> "If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth... More specifically, the combination will be searched until one nucleotide is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

It would appear that the Office readily recognizes that a search of a combination of 10 or more sequences does constitute a reasonable search and examination burden. Indeed, the pertinent policy behind this decision in § 803.04:

> "Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application."

Applicant submits that it is reasonable to apply a similar policy to the search of inventions containing peptide sequences, whose searches are performed in a similar manner.

Provisional election under 37 C.F.R. §1.143

Pursuant to 37 C.F.R. §1.143, Applicant's undersigned attorney hereby elects with traverse, the invention of Group I, claims 1-3, drawn to compositions comprising at least two immunogenic ligands, classified in class 530, subclass 300; and species SEQ ID NOs: 3 and 5, reading on claims 1-3 of Group I.

CONCLUSION

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

06/10/04
Date

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